Association of Regulatory Affairs and Pharmaceutical Regulation Professionals

INTRODUCTION OF FEES TO BE CHARGED BY THE EMA FOR PHARMACOVIGILANCE

- CONCEPT PAPER -

Dear Sirs.

As representatives of Pharmacovigilance technician professionals, we have significant concerns about the values for the fees proposed in the Concept Paper. The proposed fees for Pharmacovigilance activities (PSUR's and PASS's) are significantly higher than those proposed in the Commission's Financial Statement and the Impact Assessment that accompanied the initial 2008 proposals of Pharmacovigilance legislation. Additionally no valid reasoning has been provided that could justify a more than 10 fold increase in fees. a

Once Pharmacovigilance activities are indispensable tool for the protection of Public Health, we believe that these activities cannot be considered a unique service of pharmaceutical industry but should receive a Community funding. Nevertheless the proposed fees appear excessive, and using the Type II variation of medicines authorized by CAP as a benchmark for the assessment of some Pharmacovigilance activities (PSUR's and PASS's) is not suitable.

Comments of consultation item nº 1 to 6:

- Fees must be calculated according to the workload, the nature of the Pharmacovigilance activities and resources involved, regardless of the molecule in question, without prejudice to the particular situations of certain medicines, such as well established medicinal products, which are in the market for many years and whose payment of these values is not proportional to their resources and the time required for the evaluation of an assessment report. For this reason higher fees for these products would be unreasonable.
- The frequency of submission should be taken into account (like PSUR's submissions);

- The MAH need further guidance on how to produce a single integrated PSUR or PASS for product with more than one MAH. Which company will be responsible for producing the PSUR and evaluating the safety information? Who will sign the PSUR? How can this information be exchange between companies without data privacy issues and/or proprietary information?

Comments of consultation item nº 7:

- Again, once Pharmacovigilance include public health activities, some of these activities should at least partly financed by Community funds. On the other hand EMA's literature monitoring will not benefit all products and as relevant Pharmacovigilance technicians (QQPV, Trusted deputies and other staff) are trained in compliance with the new legislation it seems unfair to include the cost of this service in the fees charged.

Comments of consultation item nº 8 and 9:

- We agree with SME's reduction fees, however even with 50% of fee reduction difficulties still unreasonable to support, taking into account the absolute value of those fees and the economic crises that some European countries face.

Comments of consultation item nº 10:

- We also would like refer that the financial effort of some countries is substantially higher than others, and therefore the requirement for equal fees to all countries does not meet the equity standard.

APREFAR, 11th September 2012